

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	:	MDL No. 19-2875(RBK/KW)
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	:	
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This Order Relates to all Cases

SPECIAL MASTER ORDER NO. 25

June 14, 2021

THE BACKGROUND OF THIS ORDER IS AS FOLLOWS:

Plaintiffs have filed a Motion to Compel the Production of the Custodial File of Baohua Chen from Defendants, Zhejiang Huahai Pharmaceutical Co, Ltd., Huahai U.S., Inc., Prinston Pharmaceutical Inc., and Solco Healthcare US, LLC (collectively “ZHP”). (Doc 1189; 5-3-21 Hrg. Tr. (Doc. 1220) at 28:3-6).¹ ZHP has filed a Cross-Motion for Protective Order Precluding the Production of the Custodial File of Baohua Chen. (Doc. 1246.) The question of whether Mr. Chen’s custodial file should be produced has been thoroughly covered in the parties’ briefs. (*See* Docs. 1189, 1244, and 1250.)

¹ During the May 3, 2021 discovery conference, the parties were advised that Plaintiffs’ agenda letter (Doc. 1189) would be considered to have presented a motion to compel production of Mr. Chen’s custodial file.

In support of their motion to compel, and in opposition to Defendants' motion for a protective order, Plaintiffs' argue that Baohua Chen, as Founder and Chairman of ZHP, has direct knowledge of issues central to this case, and which Plaintiffs cannot learn or confirm from other sources or witnesses who have already been or will be deposed. Plaintiffs maintain that the only way to fairly probe Mr. Chen's knowledge and involvement at his deposition, currently scheduled for June 21, 22 and 23,² is to be provided his custodial file. In this regard, Plaintiffs assert that Mr. Chen played a central role in ZHP's response to the disclosure of nitrosamine contamination of valsartan, communicating directly with the FDA, participating in FDA inspections, and organizing and attending a number of meetings that included top management. (Doc. 1189 at 5; 11.) During FDA inspections, Mr. Chen informed the FDA that he "has the ultimate authority at [ZHP] and takes full responsibility for the company's operations." (*Id.*) Additionally, Plaintiffs claim that Mr. Chen was "intimately involved with ZHP's recall of Valsartan." (*Id.* at 12.) Specifically, Plaintiffs rely on a letter written by Mr. Chen to the European Directorate for Quality of Medicines (EDQM) "regarding ZHP's corrective and preventative actions in light of the recalls, addressing ZHP's efforts to correct the massive systemic deficiencies that allowed the nitrosamine contamination to occur, and requesting permission to

² While there is a pending Motion for Protective Order Precluding the Deposition of Baohua Chen (Doc. 1247), that motion and the within Motion, although related, ultimately present distinct issues.

again sell valsartan.” (Doc. 1250 at 7.) Ultimately, Plaintiffs contend, “Mr. Chen is not just a figurehead, he has direct technical knowledge and training [and] [h]e has wide experience in the product development and quality management of bulk drugs.” (Doc. 1189 at 11.)

In opposition to Plaintiffs’ motion to compel, and in support of their motion for protective order, ZHP contends that Mr. Chen’s custodial file “would only be cumulative of the information that is obtainable (and has been obtained) from the many custodial files already produced and the days of deposition testimony already submitted.” (Doc. 1244 at 1.) ZHP notes that it has produced hundreds of thousands of documents from multiple custodians and that there is little likelihood that Mr. Chen’s custodial file contains documents not previously produced. ZHP also maintains that “Mr. Chen, as ZHP’s President, functions in a managerial capacity, receiving reports and accepting decisions from the ZHP Party department heads who Plaintiffs have examined thoroughly.” (*Id.* at 1-2.) ZHP points out that “Mr. Chen focuses on setting the annual performance target approved by ZHP’s Board of Directors, the budget, and operational issues such as ensuring that departments have adequate funding and are receiving the necessary support from other departments.” (*Id.* at 4.) ZHP further asserts that “Mr. Chen is not involved in the day-to-day activities of ZHP’s API or finished dose manufacturing, testing, analytical method development.” (*Id.* at 5.) ZHP also claims that “Mr. Chen’s role in the valsartan

recall was limited to high-level oversight, and only involved instructing the recall team that they should ‘follow all the guidelines . . . to protect the patients and . . . recall the materials.’” (*Id.*) With regard to inspections, Defendants contend that “[w]hile Mr. Chen may attend the welcome and final meetings of an FDA inspection, he is not present during other stages of the FDA inspections.” (*Id.* at 15.) “Nor is Mr. Chen involved in drafting correspondence to the FDA. . . .” (*Id.*) Defendants also argue that Mr. Chen’s participation in the “Recall Group” was “limited [to] instructing the recall team that they should ‘follow all the guidelines. . . to protect the patients and . . . recall the materials.’” (*Id.* at 17.) Finally, ZHP argues that, because “Mr. Chen uses his ZHP email account in the course of carrying out his public duties,” (*id.* at 20), production of Mr. Chen’s custodial file “could expose Mr. Chen to severe criminal penalties under Chinese law given the nature of his public positions with the Chinese government and the highly confidential and sensitive state secret information that pervades his custodial file as a result.” (*Id.* at 2.)

Federal Rule of Civil Procedure 26 defines the scope and limits of discovery. Specifically, Rule 26(b)(1) provides that “[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party’s claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties’ relative access to relevant information, the parties’ resources, the importance of the discovery in resolving the

issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit.” *Id.* Pursuant to Rule 26(b)(2), the court must limit the frequency or extent of discovery otherwise allowed by these rules or by local rule if it determines that:

- (i) the discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive;
- (ii) the party seeking discovery has had ample opportunity to obtain the information by discovery in the action; or
- (iii) the proposed discovery is outside the scope permitted by Rule 26(b)(1).

In addition, “[t]he court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense[.]” Fed. R. Civ. P. 26(c)(1). In moving for a protective order, the party seeking the order “must show good cause by demonstrating a particular need for protection.” *Cipollone v. Liggett Group, Inc.*, 785 F.2d 1108, 1121 (3d Cir. 1986). Establishing “good cause” requires the movant to “specifically demonstrate [] that disclosure will cause a clearly defined and serious injury. Broad allegations of harm, unsubstantiated by specific examples, however, will not suffice.” *Glenmede Trust Co. v. Thompson*, 56 F.3d 476, 483 (3d Cir. 1995) (citing *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994)).

Plaintiffs have adequately shown that Mr. Chen had direct involvement with issues central to this case, and that the information they seek is relevant to the claims and defenses in this matter. Other “proportionality” factors, such as “the importance of the issues at stake in the action, the amount in controversy, the parties’ relative access to relevant information, the parties’ resources, [and] the importance of the discovery in resolving the issues,” Fed. R. Civ. P. 26(b)(1), favor requiring production. What is less clear is whether Mr. Chen’s custodial file is likely to possess unique, discoverable information given the volume of document production by ZHP that has occurred to date. What also remains unclear is the amount of effort required to produce Mr. Chen’s custodial file so that it could be said that “the burden or expense of the proposed discovery outweighs its likely benefit.” *Id.*

It was, of course, ZHP’s burden to show that “disclosure will cause a clearly defined and serious injury.” *Glenmede Trust*, 56 F.3d at 483. Given the fact that ZHP alone has access to Mr. Chen’s custodial file, it was better situated than Plaintiffs to demonstrate that the file would not contain relevant and unique information. It was also in a superior position to present competent evidence of the time and expense likely to be incurred to produce the file. ZHP’s failure to do so militates against granting a protective order. As was noted at the May 3, 2021 hearing, “[b]ased upon what’s been presented . . . it seems . . . that [Mr. Chen] would have unique material information,” favoring requiring “the production of Mr. Chen’s

custodial file.” (5/3/2021 Tr. 27:17-20.) Additionally, while the threat to Mr. Chen of criminal prosecution through the production of protected document is a serious concern, that threat can be minimized by ZHP withholding and/or redacting the sensitive documents and producing a log of withheld documents, just as ZHP has done with respect to documents withheld under the Chinese State Secrecy laws.³

NOW, THEREFORE, IT IS HEREBY ORDERED THAT:

1. Plaintiffs’ Motion to Compel Production of Custodial File of Baohua Chen (Doc. 1189) is **GRANTED**. The timing of the production will be addressed at the June 16, 2021 discovery conference.
2. Defendants’ Motion for Protective Order (Doc. 1246) is **DENIED**.

s/ Thomas I. Vanaskie
Hon. Thomas I. Vanaskie (Ret.)
Special Master

³ ZHP suggests that withholding and/or redacting documents could prove to be burdensome as it would need to be done with “surgical precision,” but this broad assertion is not sufficient to warrant a blanket protective order on Mr. Chen’s file. In this regard, ZHP can seek modification of this ruling if the time and expense to prevent production of protected documents proves to be overly time-consuming and expensive.